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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/543,084

01/26/2006

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03762.015900

1166

74432 7590 09/30/2009

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

09/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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DETAILED ACTION

Status of the Application

Claims 1-15 are pending in this action. Claims 1-15 are subject to a Restriction/Election requirement.

Note: Claims 2-15 are incorrectly listed as claims 3-16. There is no claim "2" present in the listing of claims. The Examiner has interpreted claims "3-16" to read as claims "2-15" for restriction purposes. The Examiner requests that the numbering of claims be corrected in the next response.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, drawn to a dispersion of crystals or granules of active substance (class 424, subclass 490).

Group II, claim(s) 10-14, drawn to a chewable soft capsule (class 424, subclasses 451, 456).

Group III, claim(s) 15, drawn to a process for the preparation of chewable soft capsules (class 424, subclass 451).

Note: Groups II and III are subject to rejoinder.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature that is lacking is the particular form of the products being claimed (i.e., granules versus capsules). Groups I-II are drawn to an intermediate-final product relationship. Regarding Groups I & III, Group I is drawn to a product (crystal or granule dispersion), whereas Group III is drawn to a process of making a

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different product (capsule). In addition, the particular forms being claimed would impart unique chemical and physiological effects, including different rates of release, dependent on the specific form being utilized.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Election of Species:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(1) Election of lipophilic vehicle:

- (a) vegetable oils
- (b) animal oils
- (c) tri-, di- or monoglycerides of fatty acids
- (d) lipolysing oils
- (e) mineral oils
- (f) (light) waxes

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(g) Vaseline

(h) silicone oil, simethicons

(i) mixtures of silicone oil and colloidal silica

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 2 corresponds to species (a)-(i).

The following claim(s) are generic: Claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the distinct species claimed are capable of imparting varying solubility rates and effects, based on the particular lipophilic vehicle employed.

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(2) Election of coating:

- (a) celluloses - ethycellulose, hydroxyethylcellulose, hydroxypropylmethylcellulose, hydroxypropylmethylcellulose acetate
- (b) acrylates - methacrylic copolymer
- (c) lipidic compounds, lipophilic compounds
- (d) behenate – polyethylene glycol; stearates – glycerol palmitostearate, glycerol stearate, PEG-32 stearate, PEG-32 palmitostearate; palmitate – cetyl palmitate
- (e) macrogol beeswaxes
- (f) glycerol

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 5 corresponds to species (a)-(f).

The following claim(s) are generic: Claim 1.

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the distinct species claimed are capable of imparting different properties and characteristics, such as varying rates of release, based on the particular coating component employed.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because the above restriction/election is complex, a telephone call to applicants to request an oral election was not made. See MPEP 812.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Mon-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615

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September 28, 2009